



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,696	03/09/2007	Stephan Christopher Pleines	70279USPCT	7419

22847 7590 12/10/2010
SYNGENTA BIOTECHNOLOGY, INC.
PATENT DEPARTMENT
3054 CORNWALLIS ROAD
P.O. BOX 12257
RESEARCH TRIANGLE PARK, NC 27709-2257

EXAMINER

THOMAS, DAVID C

ART UNIT	PAPER NUMBER
----------	--------------

1637

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

12/10/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP.SBI@syngenta.com

Office Action Summary	Application No. 10/582,696	Applicant(s) PLEINES ET AL.	
	Examiner DAVID C. THOMAS	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 20, 21, 30 and 32-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-19, 22-29, 31 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed September 27, 2010 is acknowledged. Claims 12, 16, 17, 19, 22, 23, 24 and 31 (currently amended) and claims 13-15, 18, 25-29 and 40 (original or previously presented) will be examined on the merits. Applicant apparently intends to cancel claims 1-11, 20, 21, 30 and 32-39 since the limitations of these claims have been lined out. However, since the status identifier for these claims remains "withdrawn", the intended status of these claims is not clear. Note also that the status identifier of claims 16 and 17 are marked "presently amended", while those of other amended claims is "currently amended". While it is clear what is intended, consistent use of status identifiers is requested. Finally, the status identifier of claim 40 is "new", even though this claim was previously presented. Correction of all of the claims indicated above is required in the next submission.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12-19, 23-29, 31 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claims 12-19 and 31, base claims 12 and 31 contain the newly added limitation “wherein said detected DNA fragment comprises a different recombination event than the Brassica plants Lutin, P209001, P97838, P97839 or P209002”. This limitation represents new matter since this subject matter is not described in the specification. The only references to this group of plants are found in paragraphs 114 (Example 2) and 115 (Example 3) of U.S. Patent Pub. No. 2007/0294792. However, there is no specific reference in these paragraphs to a detected DNA fragment that comprises a different recombination event than the Brassica plants identified in the amended claim and in these paragraphs.

With regard to claims 23-29 and 40, base claims 23 and 24 contain the newly added limitations “wherein the parent with said event has line stability” and “wherein said male fertile restorer parent has line stability”, respectively, with regard to the BLR1 recombination event in the male parent plant. These limitations represent new matter since this subject matter is not described in the specification. The only reference to line stability is found in paragraph 6 of U.S. Patent Pub. No. 2007/0294792. However, there is no specific reference to a male fertile restorer parent having line stability, particularly with reference to the BLR1 recombination event. Furthermore, for purposes of examination, since the term “line stability” is not precisely defined in the specification, unless specific plants cited in the prior art are specifically described as unstable, they will be interpreted as having line stability.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 recites the limitation "The method of selecting a *Brassica* plant" in claim 12. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 23-29 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Tulsieram et al. (WO 98/56948, cited on IDS).

Tulsieram teaches a method of detecting a *Brassica* plant containing a restorer gene (methods are presented for using molecular markers for determining the genotype of the Ogura restorer gene in *Brassica* plants by the techniques of random amplified polymorphic DNA (RAPD) or amplified fragment length polymorphism (AFLP) analysis, see Abstract and p. 6, lines 9-17), comprising the steps of:

Art Unit: 1637

a) obtaining a sample from a *Brassica* plant (for analysis of markers by AFLP, plant material was obtained from a winter *B. napus* population, 94CWN2133, p. 28, lines 24-26);

b) detecting in said sample a DNA fragment (AFLP analysis was performed after DNA extraction, using AFLP primers having a single selective nucleotide in a first step amplification, with a second amplification reaction performed using labeled primers, p. 29, lines 7-32; amplification products were resolved by gel electrophoresis, p. 30, lines 1-15; putative markers for the restorer gene were then sequenced, p. 30, lines 17-29), by

ii) at least one marker of bin 2, but none of the markers of bin 3 (AFLP markers included E33/M47 of bin2, but not any bin3 markers, p. 20, lines 18-23 and p. 21, lines 28-30),

wherein said detected DNA fragment comprises a different recombination event than the *Brassica* plants Lutin, P209001, P97838, P97839 or P209002 (AFLP markers detected included E33/M47 of bin2 in plant material obtained from a winter *B. napus* population, 94CWN2133, p. 20, lines 18-23, p. 21, lines 28-30 and p. 28, lines 24-26).

With regard to claim 13, Tulsieram teaches a method further comprising selecting said *Brassica* plant, or a part thereof, containing said DNA fragment (the population used for AFLP analysis was derived by crossing homozygous restorer plants with sterile plants from the same population to produce heterozygous offspring, p. 28, lines 26-28).

With regard to claim 14, Tulsieram teaches a method further comprising the step of selfing said *Brassica* plant containing said DNA fragment (the resulting heterozygous

Art Unit: 1637

offspring were then selfed resulting in a population segregating for the restorer gene, p. 28, lines 28-30).

With regard to claim 15, Tulsieram teaches a method further comprising the step of crossing said *Brassica* plant with another *Brassica* plant (the winter *B. napus* population, 94CWN2133, was obtained by crossing NW3002 and Bristol canola plants, p. 24, lines 7-9).

With regard to claim 16, Tulsieram teaches a method of selecting a *Brassica* plant, wherein said DNA fragment comprises the BLR1 recombination event (recombination events in fertile offspring plants that result in low glucosinolate *Brassica* plant lines were detected by screening for AFLP markers linked to the restorer gene, with breakpoints indicated by which markers are lost, p. 21, lines 14-26, Table 6 and Figure 3).

With regard to claims 17 and 18, Tulsieram teaches a method of selecting a *Brassica* plant, wherein said marker of bin 2 comprises E33M47, E2M4-1, E3MI-1, E4M14-1, E5M1-2, E5M4-2, or E8MI4-2 or has partial homology to E33M47, E2M4-1, E3MI-1, E4M14-1, E5M1-2, E5M4-2, or E8M14-2 (AFLP markers included E33/M47 of bin2, p. 9, lines 14-19, p. 20, lines 18-23 and p. 21, lines 28-30; note, there is no strict definition in the Specification of "partial homology" and therefore sequences having as few as two common contiguous bases may be considered to share partial homology).

With regard to claim 23, Tulsieram teaches a method for producing a fertile F1 hybrid *Brassica* plant (plants were produced and scored as either male fertile or sterile

Art Unit: 1637

based on flower phenotype, p. 24, lines 15-17 and p. 28, line 30 to p. 29, line 2) comprising the steps of:

a) determining total glucosinolate content in the male fertile restorer parent comprising the BLR1 recombination event, wherein the parent with said event has line stability, and, optionally, also in the female male sterile CMS parent (plants were determined to be fertile or sterile offspring containing or not containing the fertility restorer gene by testing for glucosinolate levels and also screening for AFLP markers indicating recombination events had occurred, with breakpoints indicating which markers are lost, p. 21, lines 14-26, p. 22, lines 4-8, Table 6 and Figure 3; note, as discussed above, the term "line stability" is not precisely defined in the specification, and unless specific plants cited in the prior art are specifically described as unstable, they will be interpreted as having line stability); and

b) crossing the female and male parents to produce F1 hybrid seed (fertile plants, as determined by AFLP analysis, were derived by crossing homozygous restorer plants with sterile plants from the same population to produce heterozygous offspring, p. 28, lines 26-28).

With regard to claim 24, Tulsieram teaches a method for producing a fertile F1 hybrid *Brassica* plant (plants were produced and scored as either male fertile or sterile based on flower phenotype, p. 24, lines 15-17) comprising the steps of:

a) detecting in seed or a plant of the male fertile restorer parent the BLR1 recombination event through marker analysis, wherein said male fertile restorer parent has line stability (recombination events in fertile offspring plants that result in low

Art Unit: 1637

glucosinolate *Brassica* plant lines were detected by screening for AFLP markers linked to the restorer gene, with breakpoints indicated by which markers are lost, p. 21, lines 14-26, Table 6 and Figure 3; note, as discussed above, the term “line stability” is not precisely defined in the specification, and unless specific plants cited in the prior art are specifically described as unstable, they will be interpreted as having line stability); and

b) crossing the female and male parents to produce F1 hybrid seed (fertile plants, as determined by AFLP analysis for Rf markers, were derived by crossing homozygous restorer plants with sterile plants from the same population to produce heterozygous offspring, p. 28, lines 26-28).

With regard to claim 25, Tulsieram teaches a method comprising the additional step of detecting in seed or a plant of the restorer parent a DNA fragment through marker analysis (AFLP analysis of markers associated with the fertility restorer gene in *Brassica* plants was performed using AFLP primers having a single selective nucleotide in a first step amplification, with a second amplification reaction performed using labeled primers, p. 29, lines 7-32).

With regard to claim 26, Tulsieram teaches a method comprising the additional step of planting said F1 hybrid seed (heterozygous offspring resulting from crossing homozygous restorer plants and sterile plants were selfed using the resulting hybrid seed and plants, p. 28, lines 26-30).

With regard to claim 27, Tulsieram teaches a method comprising the additional step of harvesting the F2 seed grown from the plant resulting from said F1 seed (seeds

Art Unit: 1637

from the F2 population 94CWN2133 were harvested and grown in a greenhouse for marker analysis, p. 13, lines 28-29 and p. 28, line 30 to p. 29, line 2).

With regard to claim 28, Tulsieram teaches a method comprising the additional step of determining total glucosinolate content in F2 seed derived from the F1 hybrid plant (plants were determined to be fertile or sterile offspring containing or not containing the fertility restorer gene by testing for glucosinolate levels, p. 21, lines 14-26, p. 22, lines 4-8, Table 6 and Figure 3).

With regard to claim 29, Tulsieram teaches a hybrid F1 Brassica plant produced by the method of claim 26 (heterozygous offspring are produced from crossing homozygous restorer plants and sterile plants, the seeds of which were used for selfing, p. 28, lines 26-30).

With regard to claim 31, Tulsieram teaches a method for producing a Brassica plant containing the BLR1 recombination event (plants were produced and scored as either male fertile, and also recombined in the Rf region to have low glucosinolate levels, or sterile based on flower phenotype, p. 24, lines 15-17 and p. 28, line 30 to p. 29, line 2) comprising the steps of obtaining a Brassica plant containing the BLR1 recombination event, wherein said Brassica plant comprises a different recombination event than the Brassica plants Lutin, P209001, P97838, P97839 or P209002 (the winter *B. napus* population, 94CWN2133, was used to obtain a homozygous restorer population, p. 24, lines 5-7 and p. 28, lines 24-27; AFLP markers detected included E33/M47 of bin2 in plant material obtained from 94CWN2133, p. 20, lines 18-23, p. 21, lines 28-30 and p. 28, lines 24-26), crossing this plant with another Brassica plant to

Art Unit: 1637

obtain hybrid seed (homozygous restorer plants were crossed with sterile plants from the same population to produce heterozygous offspring, p. 28, lines 26-28), and planting said hybrid seed to produce a Brassica plant containing the BLR1 recombination event (heterozygous offspring resulting from crossing homozygous restorer plants and sterile plants were selfed using the resulting hybrid seed and plants to produce a population segregating for the restorer gene, the seeds of which were used to produce plants that were screened for the restorer gene and scored for the flowering phenotype, p. 28, line 26 to p. 29, line 2).

With regard to claim 40, Tulsieram teaches a method comprising the additional step of detecting in seed or a plant of the restorer parent a DNA fragment through marker analysis (markers associated with the fertility restorer gene in parent *Brassica* plants such as NW3002, used to generate the restorer population 94CWN2133, were screened for linkage to the restorer gene, including the marker E33/M47, p. 24, lines 7-9 and Table 6).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1637

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tulsieram et al. (WO 98/56948) in view of Tulsieram et al. (GenBank Accession No. BD192151.1 (2003), herein referred to as Tulsieram (2003)) and further in view of Lowe et al. (Nucleic Acids Res. (1990) 18:1757-1761).

Tulsieram teaches the limitations of claims 12-18, 23-29, 31 and 40, as discussed above.

With regard to claim 19, Tulsieram also teaches a method of detecting a *Brassica* plant (methods are presented for using molecular markers for determining the genotype of the Ogura restorer gene in *Brassica* plants by the techniques of random amplified polymorphic DNA (RAPD) or amplified fragment length polymorphism (AFLP) analysis, see Abstract and p. 6, lines 9-17), further comprising the step of detecting in said sample a DNA fragment obtainable by PCR amplification (AFLP analysis was performed after DNA extraction, using AFLP primers having a single selective nucleotide in a first step amplification, with a second amplification reaction performed using labeled primers, p. 29, lines 7-32).

With regard to claim 22, Tulsieram teaches a method of screening a *Brassica* plant to determine whether it contains the BLR1 recombination event (recombination events that result in low glucosinolate *Brassica* plant lines were screened for AFLP markers linked to the restorer gene, with breakpoints indicated by which markers are lost, p. 21, lines 14-26 and Figure 3), comprising extracting DNA from said *Brassica* plant (DNA extraction was performed using a modified CTAB extraction protocol, p. 29, lines 7-13), subjecting the extraction to a polymerase chain amplification reaction in the presence of DNA fragments represented (AFLP analysis was performed, using AFLP primers having a single selective nucleotide in a first step amplification, with a second amplification reaction performed using labeled primers, p. 29, lines 15-32).

However, Tulsieram does not teach a method of polymerase chain amplification using primers 1159 (SEQ ID NO:13) and 1160 (SEQ ID NO:14), whereas said DNA fragment is not amplified by the primers PR0004F (SEQ ID NO:19) and PR0004R (SEQ ID NO:20).

Tulsieram (2003) teaches a nucleotide sequence used for genotype determination of the Ogura Rf gene in *Brassica Napus* by molecular marker analysis, and includes a 143-base sequence that contains primer binding sites for SEQ ID NO: 13 (positions 2-24) and SEQ ID NO: 14 (positions 138-116) of the instant invention, but not for SEQ ID NOS: 19 and 20 (see search results below):

```
RESULT 2
BD192151
LOCUS      BD192151                143 bp    DNA        linear    PAT 17-JUL-
2003
DEFINITION Use of molecular markers for genotype determination of the ogura
Rf
            gene in brassica napus.
ACCESSION  BD192151
```

Art Unit: 1637

VERSION BD192151.1 GI:33001890
 KEYWORDS JP 2002512523-A/14.
 SOURCE Aspergillus oryzae
 ORGANISM Aspergillus oryzae
 Eukaryota; Fungi; Dikarya; Ascomycota; Pezizomycotina;
 Eurotiomycetes; Eurotiomycetidae; Eurotiales; Trichocomaceae;
 mitosporic Trichocomaceae; Aspergillus.

REFERENCE 1 (bases 1 to 143)
 AUTHORS Tulsieram, L.K. and Riddell, C.M.
 TITLE Use of molecular markers for genotype determination of the ogura
 Rf gene in brassica napus
 JOURNAL Patent: JP 2002512523-A 14 23-APR-2002;
 PIONEER HI BRED INTERNATIONAL INC

COMMENT PN JP 2002512523-A/14
 PD 23-APR-2002
 PF 10-JUN-1998 JP 1999501170
 PR 10-JUN-1997 CA 2206673
 PI LOMAS K TULSIERAM, CHRISTINE M RIDDELL
 PC C12Q1/68, A01H1/04
 CC Strandedness: Double;
 CC Topology: Linear;
 CC /note= 'E33M47 (or E33XM47AI)'
 FH Key Location/Qualifiers.

FEATURES Location/Qualifiers
 source 1. .143
 /organism="Aspergillus oryzae"
 /mol_type="genomic DNA"
 /db_xref="taxon:5062"

ORIGIN

Query Match 100.0%; Score 23; DB 9; Length 143;
 Best Local Similarity 100.0%;
 Matches 23; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 TAACAAAATAGAGGGAGAGGATG 23
 |||||
 Db 2 TAACAAAATAGAGGGAGAGGATG 24

RESULT 2
 BD192151/c
 LOCUS BD192151 143 bp DNA linear PAT 17-JUL-2003
 DEFINITION Use of molecular markers for genotype determination of the ogura
 Rf gene in brassica napus.
 ACCESSION BD192151
 VERSION BD192151.1 GI:33001890
 KEYWORDS JP 2002512523-A/14.
 SOURCE Aspergillus oryzae
 ORGANISM Aspergillus oryzae

Art Unit: 1637

```

Eukaryota; Fungi; Dikarya; Ascomycota; Pezizomycotina;
Eurotiomycetes; Eurotiomycetidae; Eurotiales; Trichocomaceae;
mitosporic Trichocomaceae; Aspergillus.
REFERENCE      1 (bases 1 to 143)
AUTHORS        Tulsieram,L.K. and Riddell,C.M.
TITLE          Use of molecular markers for genotype determination of the ogura
Rf
JOURNAL        gene in brassica napus
                Patent: JP 2002512523-A 14 23-APR-2002;
                PIONEER HI BRED INTERNATIONAL INC
COMMENT        PN    JP 2002512523-A/14
                PD    23-APR-2002
                PF    10-JUN-1998 JP 1999501170
                PR    10-JUN-1997 CA    2206673
                PI    LOMAS K TULSIERAM,CHRISTINE M RIDDELL
                PC    C12Q1/68,A01H1/04
                CC    Strandedness: Double;
                CC    Topology: Linear;
                CC    /note= 'E33M47 (or E33XM47AI) '
                FH    Key          Location/Qualifiers.
FEATURES
    source      Location/Qualifiers
                1. .143
                /organism="Aspergillus oryzae"
                /mol_type="genomic DNA"
                /db_xref="taxon:5062"
ORIGIN
Query Match          100.0%;  Score 23;  DB 9;  Length 143;
Best Local Similarity 100.0%;
Matches 23;  Conservative 0;  Mismatches 0;  Indels 0;  Gaps
0;
Qy          1 CAAGATTATAGCTACCTAACAGG 23
            |||
Db          138 CAAGATTATAGCTACCTAACAGG 116

```

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to design amplification primers for detection of markers for genotyping the Ogura Rf gene in *Brassica napus* based on the sequence taught by Tulsieram (2003) since this sequence is known to contain markers associated with the fertility restorer gene. Thus, an ordinary practitioner would have been motivated to use such a sequence in order to design primers that are specific for a marker that is associated with the presence of the restorer gene in *Brassica* plants. The ability to

Art Unit: 1637

detect such markers allows breeders to detect the presence of the restorer gene in offspring plants at an early stage of development instead of having to wait until the plants mature to determine whether the plants produce normal flowers and pollen, an indication of fertile plants (Tulsieram, p. 2, lines 19-23).

In the recent court decision *KSR International Co. v. Teleflex Inc.*, 82 127 SCt 1727 (2007), the U.S. Supreme Court determined that if the combination of the claimed elements was “obvious to try” by a person of ordinary skill, this might show that such a combination was obvious under §103. Regarding “obvious to try”, the Court stated:

“A person of ordinary skill is also a person of ordinary creativity, not an automaton. The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was “obvious to try.” *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.”

Since the claimed primers simply represent structural homologs of the oligonucleotides taught by Tulsieram (2003), which are 100% derived from sequences expressly suggested by the prior art of Tulsieram as useful for primers for the detection and genotyping of *Brassica* plants containing the fertility restorer gene and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers are *prima facie* obvious over the cited references in the absence of secondary considerations.

With regard to the issue of equivalence of the primers, MPEP 2144.06 notes “Substituting equivalents known for the same purpose. In order to rely on equivalence

Art Unit: 1637

as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

With regard to the issue of reasonable expectation of success in using such equivalents at the time the invention was made, as shown in Lowe, one of skill in the art was clearly aware of the factors involved in designing amplification primers from a known sequence, and would have routinely and predictably designed any such primers. Specifically, Lowe teaches a computer program based on a set of rules which take into account both the sequence of the primers and the amplified region of DNA, such that primer-to-target hybridization is enhanced, while facilitating attainment of full-length extension products by minimizing non-specific product formation and self-priming (see Abstract and p. 1757, column 2, line 33 to p. 1758, column 1, line 41). The program has been tested on a variety of gene products for RT-PCR, for both total and cytoplasmic RNA samples prepared by several different methods (Lowe, p. 1758, column 2, last 2 lines). "Experimental testing has shown that all the amplification products specified by these primers are of the predicted size and also hybridize with the appropriate cDNA or internal oligonucleotide probe" (Lowe, p. 1769, column 2, line 4-8).

Response to Arguments

10. Applicant's arguments filed September 27, 2010 have been fully considered but they are not persuasive.

Applicant argues that the objection to the specification should be withdrawn since the specification on page 2 is amended to read as originally filed in the PCR document. The Examiner agrees and the objection is withdrawn. In addition, Applicant argues that the objection to claims 19 and 22 should be withdrawn since the claims have been amended to include SEQ ID NOs associated with primer sequences. The Examiner agrees and the objection is withdrawn.

Applicant then argues that the rejection of claims 16-18 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention should be withdrawn based on amendments to the claims. The Examiner agrees that the amendments clarify some the rejected claims and the rejection is thus withdrawn for claims 16 and 17 only. However, the rejection is maintained for claim 18 since this claim recites the limitation "The method of selecting a Brassica plant...", for which there is insufficient antecedent basis in claim 12.

Applicant then argues that the rejection of claims 12-18, 23-29, 31 and 40 under 35 U.S.C. § 102(b) as being anticipated by Tulsieram et al. (WO 98/56948) should be withdrawn since the reference no longer teaches all the limitations of the claims as amended. In particular, Applicant argues that Tulsieram does not teach that the DNA fragment comprising a different recombination event than the Brassica plants Lutin,

Art Unit: 1637

P209001, P97838, P97839 or P209002 and also fails to disclose “the parent line with said event has line stability”. The Examiner asserts that Tulsieram teaches methods to detect AFLP markers, including E33/M47 of bin2 in plant material obtained from a winter *B. napus* population, 94CWN2133, p. 20, lines 18-23, p. 21, lines 28-30 and p. 28, lines 24-26. There is no teaching in Tulsieram that this detected marker is associated with Brassica plants Lutin, P209001, P97838, P97839 or P209002 in any way. Furthermore, since the term “line stability” is not precisely defined in the specification, the claims were interpreted to include plants that are not specifically described in the prior art as unstable. Without further arguments that explain how Tulsieram fails to teach the limitations of the claims as amended, the 102(b) rejection of claims 12-18, 23-29, 31 and 40 is maintained.

Applicant then argues that, with regard to claim 18, the Examiner has interpreted the phrase “partial homology” too broadly and that such an interpretation would make any genes homologous. As previously stated, the Examiner asserts that since no precise definition of “partial homology” is provided, the claim is interpreted correctly. The Examiner agrees that the term “homologous” is widely accepted in the art as meaning sequences are identical in a particular region or locus. However, “partial homology” requires a more precise definition that is not otherwise universally applied or accepted.

Applicant then argues that the rejections of claims 19 and 22 under 35 U.S.C. § 103(a) as being obvious over Tulsieram in view of Lowe should be withdrawn since the results obtained with the claimed primers represent unexpected results. In particular,

Art Unit: 1637

Applicant argues that despite having knowledge of the 143-bp fragment taught by Tulsieram, the likelihood of success for the ordinary practitioner would not be very high since a number of markers tested in three different bins were not capable of identifying the material of the present invention. The Examiner asserts that the instant claims cite detection of a DNA fragment obtainable using primers 1159 and 1160. Since the fragment contains the Ogura Rf restorer gene, and also contains binding sites for primers 1159 and 1160, it would be obvious to try primers that amplify the portion of the fragment that contains the restorer gene. Since the fragment is not exceedingly large, primer design software available at the time of the invention, such as that taught by Lowe, would assist one of skill in the art in designing a relatively small number of primers pairs that would successfully amplify the fragment. Therefore, the 103 rejection is maintained.

Summary

11. Claims 12-19, 22-29, 31 and 40 are rejected. No claims are allowable.

Conclusion

12. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 1637

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320 and whose fax number is 571-273-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David C Thomas/
Examiner, Art Unit 1637

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637